Health Policy Impact in Real Time–
Emerging Initiatives for Duke-Margolis

2024 Issues, Initiatives, and Impact Report

Duke | MARGOLIS INSTITUTE *for* Health Policy

Many Know Our Work Through the Lens of a Single Health Policy Project or Issue.

Here we share more of what we do and the foundational work behind our big ideas.

Duke

MARGOLIS INSTITUTE *for*
Health Policy

About the
Duke-Margolis Institute

The Duke-Margolis Institute for Health Policy is committed to improving health, health equity, and the value of health care through practical, innovative, and evidence-based policy solutions. With programs in health policy education, research, and innovation, and in partnership with experts across Duke University and its health system, Duke-Margolis works to ensure that quality, equitable health care is accessible and affordable for everyone.

Founded in 2016 through a generous gift—and continued support—from Robert J. Margolis M.D.'71, H.S.'72, Lisa Margolis, the Margolis Family Foundation, and Duke University, Duke-Margolis is a trusted, independent voice in complex health policy conversations. Through health policy analysis and development, the Institute advances actionable and effective solutions to address the most daunting health care challenges.

As Duke University's hub for health policy education, Duke-Margolis provides experiential, interdisciplinary learning sought after by both undergraduate and graduate students University-wide. The Institute prepares its students to apply a critical health policy lens to their professional and personal lives—to be changemakers who make health care better.

In recognition of its impact and importance to the University's future vision, Duke elevated **Duke-Margolis to an Institute**—an important achievement as Duke celebrates its centennial. This support for the Duke-Margolis mission, its work, and Duke's leadership in health policy is a great capstone to the extraordinary seven-year journey of this University-wide and nation-wide interdisciplinary initiative.

The Duke-Margolis Institute is a key component of Duke Health, which encompasses the world-class academic health care and research of the Duke University Health System, Duke University School of Medicine, Duke University School of Nursing, Duke-NUS Medical School, Duke Global Health Institute, and Duke-Margolis. Together, through the integration of its education, research, and clinical care missions, Duke Health is steadfast in its dedication to improving the lives of all who come to us for hope, health, and healing. We do so by elevating standards of care; conducting breakthrough research and discovery; teaching and training the next generation of providers; and strengthening global and community health.

"As we celebrate the university's Centennial, recognizing Duke-Margolis with institute status also advances our university-wide efforts to have a transformative impact on the future of health and health care."

**Duke University President
Vincent E. Price**

We Impact Health Policy in Real Time and Reflect the Duke Approach—

Engaging multidisciplinary teams, giving student exposure to real issues, and solving actual problems beyond academics.

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Our Approach

Duke University and Duke-Margolis are uniquely positioned to lead health policy efforts to jointly address the most important and timely challenges of the "biomedical century," a time when the world is expected to see unprecedented scientific and technical advancements. At the same time, we confront massive, persistent gaps between what should be possible through improving technologies and the reality of current public and population health, which reflect enduring, and in many contexts, widening disparities in access to care and health outcomes. Health policies and reforms to reduce inequities in health outcomes, improve the affordability and value of health care, maintain the pace of equitable biomedical innovation, and address the global demographic shifts of population aging are both badly needed and challenging to develop and implement effectively.

Strategic positioning of Duke-Margolis faculty members and research teams as a university-based research hub with a presence in both Durham, NC, and Washington, DC, has laid a strong foundation for a distinctive university-wide approach to address these challenges. Through our innovative interdisciplinary model, we leverage the talents of Duke faculty, students, and research staff, while constructively engaging the public and private sectors and the broader health policy community in advancing innovative, evidence-based solutions.

Through this approach and interdisciplinary model, Duke-Margolis seeks to analyze and formulate health policy in three core focal areas:

- **Transform Health Care** so that it is more accessible, affordable, equitable, and capable of delivering higher quality and value

- **Drive Biomedical Innovation** to improve how drugs, devices, diagnostics, and medical services are developed, paid for, and used

- **Educate the Next Generation** of health care leaders

Across each of these three areas, the Institute provides guidance and strategic analysis related to 21st century public health, health equity, and global health policy solutions.

Grounded in our focus areas to transform health care, drive biomedical innovation, and educate the next generation of health leaders, Duke-Margolis has prioritized five emergent issues for 2024 that will have significant impact on health care.

The Duke-Margolis 2024 Emerging Initiatives are the work ahead.

Our robust health policy portfolios are our foundation.

We are ready to do more.

Our 2024 priorities are to:

- Improve health in North Carolina and the American South

- Ensure a equitable, affordable pathway to cell and gene therapy

- Support development of implementation of practical and inclusive digital health

- Equip future health care leaders with the right tools and skills to solve complex health care problems

- Map a new collaborative path forward for public health
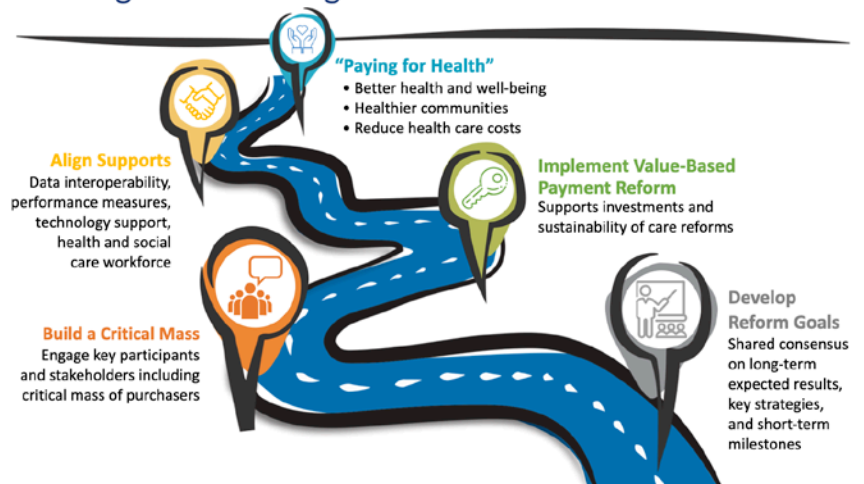
Health Care Transformation

Expanding and Spreading State-Based Transformation in and Beyond North Carolina to Improve Health in the South

North Carolina is a leading national model for the shift from "paying for health care services" to "paying for health." In the past five years, North Carolina policymakers and health care leaders have implemented significant bipartisan health reforms, leading the nation in building innovative programs and supporting infrastructure, especially related to addressing children and families' health and resource needs (e.g., housing, food) through coordinated, cross-sector models.

The Need

North Carolina now needs continued commitment and funding to power transformational change in health care practices in partnership with patients, families, and community-based organizations—and assistance to ensure a smooth journey through practical evaluation of reforms, identification of best practices, and strategies to spread innovation. Continued investment and support will help North Carolina deliver on the promise of better health, health equity, and health care affordability. This roadmap for North Carolina can serve as a guide for progress in other states in the American South.

Leading State and Regional Health Care Transformation

Align Supports — Data interoperability, performance measures, technology support, health and social care workforce

"Paying for Health"
- Better health and well-being
- Healthier communities
- Reduce health care costs

Implement Value-Based Payment Reform — Supports investments and sustainability of care reforms

Build a Critical Mass — Engage key participants and stakeholders including critical mass of purchasers

Develop Reform Goals — Shared consensus on long-term expected results, key strategies, and short-term milestones

Our extensive and deepening work in North Carolina can be further strengthened and extended to other states in the American South. These future expansions are important given that residents in the American South face higher rates of chronic disease, substance use, and have lower life expectancy than the rest of the country. People of color are a larger share of the population in the South than in the other U.S. states, and rural communities in the South are growing. These diverse populations are implementing innovations in community partnerships and care delivery to overcome historical and systemic barriers to high-quality health care and reduce disparities in health outcomes.

Why This Work Matters

State policymakers and health care leaders across the South need help identifying strategies to make it easier for everyone to access the health care they need and for health care providers to provide the best care for patients. Through research and partnerships with community organizations, state officials, and health care leaders, Duke-Margolis is implementing programs to develop and evaluate what strategies work, aiming to translate evidence into actionable steps that states can implement easily. To accelerate effective reform, Duke-Margolis helps turn strategic vision into practical policy and care delivery models.

Duke-Margolis is uniquely positioned for this work given our deep experience and connections in health policy, especially payment reform and the development of new models and care redesign; significant clinical expertise and access to a "learning laboratory" through collaborations between Duke-Margolis and leading experts at Duke Health, including Duke-Margolis faculty leadership in primary care transformation; our respected role as a neutral convener in North Carolina, other states, and nationally that can bring together diverse groups to examine complex health and social care issues; and our existing partnerships, infrastructure, and expertise in state-based health reform efforts.

For example, Duke-Margolis has helped build an innovative, cross-sector model from the ground up. NC Integrated Care for Kids (NC InCK) is a new state payment and health care delivery model focused on 100,000 children insured by NC Medicaid. NC InCK leadership are integrated in Duke-Margolis and bring expertise in child-serving systems, collaboration with school districts, Medicaid population health, and pediatric value-based payment models. The policy reforms, infrastructure supports, and implementation best practices stemming from this program can be applied to other state and federal health and social care programs for children and families.

Given Duke-Margolis's track record helping guide bipartisan health reforms in North Carolina, historically a "purple" political state, we are uniquely positioned to work with state-based partners to identify shared reform goals, build trust, and identify and align value-based payment reforms and infrastructure supports to realize the vision of "paying for health" rather than health care.

Our work is helping to support North Carolina in building an innovative and coordinated health care and social service system.

Finding Solutions

Duke-Margolis aims to launch the North Carolina Health Reform Collaborative to advance state health reform goals through:

- **Rapid response research and policy analysis** to help guide short-term decision-making to achieve measurable progress on health equity and affordability,

- **Evaluation and evidence generation** to develop, assess, and improve effective and equitable payment and delivery reforms that help providers focus on caring for patients, and

- **Stakeholder engagement and education** to assure all perspectives and insights contribute to progress.

Duke-Margolis is working to expand these capabilities and findings to support state health care transformation policy in other Southern states:

- **Applying these same activities to our growing state partnerships in the American South,** including in Texas, Arkansas, and Louisiana. We are convening safety net health care organizations, including federally qualified health centers, payers, and other stakeholders to identify opportunities to improve safety net care and accountable care reforms in Texas. In Arkansas and Louisiana, we are exploring opportunities to help build a path forward for value-based care reforms in collaboration with federal partners.

- **Expanding our efforts in North Carolina to more regional capabilities and collaborations, to improve health across the American South.** As more Southern states consider Medicaid expansion, Duke-Margolis and respective state-based partners can play a key role in helping identify and advance bipartisan goals for needed health reforms across the South. Duke University faculty and researcher expertise, along with student and trainee engagement, will further expand the breadth of research and engagment to improve health in the American South

Duke-Margolis has prioritized Expanding and Spreading State-Based Transformation in and Beyond North Carolina to Improve Health in the American South as an opportunity for pioneering funders to name and impact new student initiatives and scholarships focused on state-based health care transformation, expand Duke's community of health policy researchers and faculty, and establish a Duke Health Policy Action Fund that will provide start-up support for innovative health policy scholarship and solutions for the most pressing challenges in North Carolina and across the American South.

Only Duke has the unique focus and practical health policy approach to improve health in the American South

Our Foundational Work

As the state implements Medicaid expansion, and with our work to help NC Medicaid, Medicare, and private insurers launch NC's "Making Care Primary" initiative—a federally supported multi-payer initiative to advance primary care—new opportunities exist for synergies in reforms affecting kids, adults, and families.

North Carolina Integrated Care for Kids

A federally funded, child-focused health care delivery and payment pilot aims to advance better long-term health outcomes for children and families through care models and payment mechanisms that identify children who are at risk of poor health outcomes earlier, and making these models an integral part of Medicaid reform. Importantly, NC InCK is using health care, juvenile justice, and education data to identify children and families in need of coordinated interventions, connecting them to integrated, longitudinal care management services and ensuring cost-effective stewardship of health care dollars. The InCK model is being implemented across five central NC counties, with lessons learned informing statewide scaling after the award period is complete in 2026.

Practical Lessons for Implementing the Healthy Opportunities Pilots

In one of the first U.S. programs of its kind, North Carolina's $650 million Healthy Opportunities Pilots (HOP) program is the nation's most expansive Medicaid program to address health-related social needs related to food, housing, transportation, and interpersonal safety and toxic stress. HOP is establishing an infrastructure that identifies social needs and makes connections to supported community-based organizations and other resources for 29 evidence-based interventions to address these needs in 33 of NC's 100 counties. Duke-Margolis evaluated the lessons learned and offers recommendations for engaging, training, and partnering with providers across health and social service sectors; sustaining the funding and organizational capacity to continue this work longer than program funding; and leveraging data and technology.
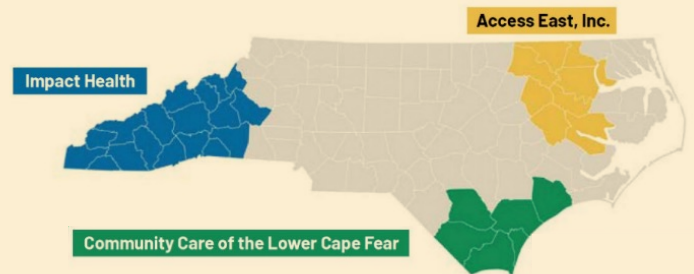
Duke Primary Care Transformation Initiative

Duke-Margolis is helping NC Medicaid, Medicare, and private insurers launch NC's "Making Care Primary" initiative, a federally supported multi-payer initiative to advance primary care and new opportunities for reforms affecting kids, adults, and families. The Duke Health Primary Care Transformation Initiative for North Carolina aspires to bring these programs and activities together as insights that can extend to other states and health care organizations and can create more momentum for longer-term health transformation. Supporting Duke Health's efforts to transform its own primary care capabilities in line with state and national goals, Duke-Margolis faculty are serving in important roles in the health system's new initiatives to integrate its physician practices and shift toward more population-focused care delivery models, while retaining leadership in academic medical research and cutting-edge specialized care.

NC State Transformation Collaborative

Duke-Margolis provides technical assistance to the Health Care Payment Learning and Action Network (LAN) in its State Transformation Collaboratives—initiatives in Colorado, California, Arkansas, and North Carolina that focus on promoting alignment in payment models, advancing primary care, and improving equity through better data and other initiatives. Duke-Margolis, in partnership with the NC Department of Health and Human Services (NC DHHS), LAN, and the Centers for Medicare & Medicaid Services (CMS), convenes North Carolina's State Transformation Collaborative (NC STC), which is focused on multistakeholder alignment for value-based care, including performance measurement, data sharing, and health equity in an effort to strengthen coordinated and accountable primary care that improves well-being. Working with NC STC lead partners, Duke-Margolis developed an initial pathway to improve population health, health equity, and patient and provider experiences while reducing costs. Over the next year, Duke-Margolis and lead partners will continue to convene stakeholders from across the state to refine the NC STC Alignment Proposal and implement practical, concrete steps to advance primary care and health equity in the state.

NC Health Care Reform Executive Roundtable

Launched by Duke-Margolis in 2019, the Roundtable brings together executive leaders from the NC DHHS, the NC Department of Information Technology, major health systems, primary care associations, health plans, and private business to translate shared interest into practical collaborative action in such areas as behavioral health integration into primary care and reducing health care administrative burdens. The Roundtable is regarded by members and other stakeholders as an important resource to help inform and execute value-based payment and population health improvement strategies across the state. Leveraging the Roundtable will facilitate the strategic vision and buy-in for interventions to advance health care transformation and health equity.

Engaging Community Members in Focusing Value-Based Payment on Improving Health Equity

In 2023, Duke-Margolis established a Community Advisory Council to bring together representatives from organizations advocating for and/or working to address the health and resource needs of historically marginalized populations to provide guidance on timely policy research and inform value-based care transformation in North Carolina. Our work to-date has helped demonstrate the importance of centering community voices and the voices of people with lived experience to improve health care transformation efforts.

Advance Our Work

Duke-Margolis aims to launch the North Carolina Health Reform Collaborative to expand our state-based health care transformation policy focus. With additional support, Duke-Margolis could expand our research and impact in state-based health reform and primary care transformation. More research is needed in key areas, including how to improve access to care for older adults and rural populations, connect primary and specialty providers, address health-related social needs, and advance long-term health outcomes for children. With more support, we also could engage more consistently with patients and community groups to increase community-informed research and ensure patient preferences and needs are represented through our analyses.

2024 Issue, Initiatives, and Impact Report

Biomedical Innovation

Duke-Margolis Cell and Gene Policy Initiative

Leveraging cutting-edge medical science, cell and gene therapies now offer new options for patients with previously untreatable conditions, and are poised to revolutionize the treatment of genetic disorders, cancers, and potentially many chronic diseases. The pipeline of cell and gene therapies is expanding—with thousands of active trials globally, targeting oncology, central nervous system disorders, infectious diseases, sickle cell anemia, and other conditions.

Despite this potential, significant challenges exist to advance these novel treatments from labs to the bedsides of the patients with serious and life-threatening conditions that they are designed to help.

The Need

Access to gene and cell therapies to alleviate suffering and death is challenged by payment and delivery models that have been designed primarily for chronically-administered treatments and paying for "downstream" complications, not for potentially one-time therapies that substantially alter or eliminate the patient's underlying health risk. In particular, the high upfront price of these treatments can significantly impact the budgets of public—particularly state Medicaid programs— and private insurers, creating barriers to their adoption.

Because the treatments are relatively new, their long-term benefits and risks are unclear after initial approval, and with further progress in manufacturing and administration, will likely evolve over time. These uncertainties present challenges for payers, health care providers, and patients seeking the best—and in some cases, the only—option for treatment. There is a need for better and more reliable postmarket monitoring and evidence development systems for cell and gene therapies can refine procedures, identify and avoid safety issues, and improve effectiveness.

Also, manufacturing and treatment processes of cell and gene therapies is generally complex, bespoke, and costly. The Food and Drug Administration (FDA) and other global regulatory agencies have implemented new regulatory initiatives and are considering further regulatory reforms to address their long-term safety, efficacy, manufacturing standards, and approval pathways. However, a major gap remains between current manufacturing and the potential for much more efficient and automated manufacturing that regulatory, payment, and coverage policies could help address, and encourage the development and the adoption of more standardized, well-characterized, and efficient approaches that can be applied to multiple conditions.

Leveraging Cutting-Edge Medical Science

Why This Work Matters

We are at a crucial point with new adoptions of innovative but high-priced therapies, along with interest from policy-makers and patients.

Duke-Margolis has the complementary research perspectives and expertise to address the complexities of cell and gene therapy. We have studied these issues for a range of other technologies and have already built a body of work that explores payment models and postmarket evidence generation.

Duke-Margolis has built trusted networks with the stakeholders that need to work together towards issues of access and outcomes. We work closely with the Food and Drug Administration and Centers for Medicare & Medicaid Services and have multi-stakeholder collaborations focused on clinical trial transformation, supply chain, payment models, and real-world evidence generation, along with a new roundtable focused on pricing and competition policy. Cell and gene therapies will bring together all of these issues and will require the involvement and commitment of stakeholders across the health ecosystem to find solutions that address both innovation and access for patients.

Duke-Margolis, through its emphasis on cell and gene therapy policy, will build on our existing work and networks to launch a robust body of policy research. Duke-Margolis' expertise and work related to innovative product regulation, manufacturing and supply chains, collaborative strategies to improve the development of real-world evidence, and value-based payment models for medical products and person-centered care provides a foundation for addressing the range of issues that affect access and affordability of these potentially curative therapeutics.

By initiating a range of research activities that focus on key policy issues affecting the innovation, manufacture, regulation, patient outcomes, equitable access, and costs of cell and gene therapies in the United States and globally, we will surface evidence-based, real-time solutions to help ensure equitable and efficient access to these promising treatments.

Finding Solutions

Duke-Margolis is working to expand our cell and gene therapy policy focus in important areas.

- **Through a cell and gene therapy policy roundtable.** In 2024, Duke-Margolis is seeking to launch a new initiative dedicated to enhancing the opportunity and accessibility of cell and gene therapies for patients. This work would bring together policymakers, regulators, payers, manufacturers, patients, and health care systems—and our Duke-Margolis team—to address key policy issues affecting the innovation, development, and costs of cell and gene therapies. The roundtable would meet throughout the year to discuss priorities, identify and inform priority policy research questions, and support our analyses and recommendations in this space.

- **Through a comprehensive policy research plan.** As part of this initiative, Duke-Margolis aims to address key policy research studies that address the access, equity, and value of cell and gene therapies. Research topics are likely to include:

  - Regulatory policies and innovative payment and coverage models to address financial obstacles to cell and gene therapies, such as:
    - insurance risk associated with relatively rare but high-cost genetically treatable conditions, especially for Medicaid plans and employers;
    - one-time payment concentration;
    - uncertainty about long-term safety and durability;
    - manufacturing complexity and high cost of goods sold;
    - high costs of therapy administration and patient management, and
    - lowering these costs through the development of reliable platforms;

We are committed to developing and supporting the implementation of practical and inclusive digital health.

- Supporting infrastructure to measure and improve outcomes that matter most to patients and their families, including:
  - strategies to track and improve the long-term safety and effectiveness of cell and gene therapies;
  - long-term management and care coordination for treated patients;
  - incentives and supports to develop and sustain a routine and robust post market evidence infrastructure; and
  - capabilities to address structural barriers and inequities in access to transformative therapies.

Our research will aim to provide timely support for public initiatives, such as the Center's for Medicare and Medicaid Services' CMS CMMI pilot program to provide a voluntary template and standards for state Medicaid programs to negotiate outcome-based agreements with manufacturers of sickle cell therapies, and facilitate private- and public-private action where needed, e.g., to augment existing gene therapy postmarket registries to improve evidence on the reliability and efficiency of these therapies.

Enabling the Digital Health Revolution

Emerging Initiative

Digital health has the potential to make transformative progress in achieving more accessible, efficient, and personalized health care. Remote tracking apps and devices empower individuals to monitor their health in real-time, fostering preventive care and enabling early intervention. Artificial Intelligence (AI) has captured broad attention and inspired a range of notable commercial and policy-related activities across the health care industry. Generative AI is not only increasingly being used in health care to reduce administrative burdens and operational costs; it is also powering clinical care tools to speed triage, improve diagnosis, help create personalized treatment plans, and assist in providers working at the top of their license.

AI can also empower patients to better engage in their health care and shared decision-making. Finally, AI tools can potentially bring down costs and spread access to clinical research and evidence generation, by helping organizations and their interested patients become more "research ready" in terms of data quality, patient engagement, and support for high-quality research practices.

The Need

If care isn't taken, AI tools could exacerbate existing challenges in our health systems. AI can perpetuate and scale clinical and operational inequities in health care. It can be used to accelerate the "arms race" in coding and documentation to support coverage and payment. Without adequate human supervision and reasonable guardrails (e.g., governance and oversight processes within health care organizations), it could lead to inappropriate or biased clinical decisions.

The Duke-Margolis focus is to help to balance opportunities for rapid and valuable innovation with safety and avoiding bias, grounded in what is technically and practically possible for different stakeholders, and strengthening the ability of health care organizations, regulators, and payers to identify what works and to detect and address safety or bias issues.

Why This Work Matters

AI development and adoption is at a critical point, where innovation and use should be encouraged while maintaining guardrails for safety as we learn more about these tools and their implementation. Additionally, this is a growing field with many policy components, e.g., FDA regulation of AI-enabled "products" (over 700 approved so far), ONCHIT requirements for certified electronic health records (EHRs) to provide key data elements to help health care organizations assess AI capabilities added to EHRs, and many AI tools being developed within health care organizations or collaborating organizations.

Through the Duke-Margolis digital health portfolio, we are committed to developing and supporting the implementation of practical and inclusive digital health and AI policies that increase evidence-based innovation and improve health outcomes, equity, and affordability while protecting patients. Duke-Margolis' researchers combine expertise in technology with knowledge of regulation, payment, and evidence development. We have conducted expensive research on evidence generation and assurance, market incentives, payment models, and coverage decisions and are well-positioned to be a leader in AI policy discussions and strategies.

Importantly, there needs to be near real-time translation between policy-makers, developers, and users to ensure that policy is moving with practice.

Finding Solutions

Duke-Margolis has an opportunity to further engage stakeholders and build on our work to date to assess what is needed, what is possible, and what is practically feasible for different parts of the ecosystem. In a time where creativity and rigor are both needed, Duke-Margolis has become an active participant in a range of national and global initiatives and can serve as a convener to identify potential best practices and policy options. Through our work with regulators, payers, manufacturers, patients, and health care end-users, we can advance our work as a trusted voice in a complex and ever evolving field.

Duke-Margolis is undertaking a range of policy initiatives to help fulfill the potential of the digital health revolution to improve health, particularly in the health AI and mHealth (remote monitoring) space, prioritizing projects that:

- **Create innovative solutions** to the unique development, regulatory, and reimbursement challenges inherent in these products, while prioritizing safety, access, and effectiveness and value

- **Emphasize the importance of representation and inclusion** in the development and deployment of digital health technologies, to foster equitable health outcomes

- **Advance high-performing digital capabilities** through effective practices for sharing quality data and conducting timely, feasible evaluations to provide reliable evidence that these products are working as expected

- **Promote transparency** regarding the development, intended use, and performance of digital health technologies

Duke-Margolis is working to expand our digital health focus in important areas.

- **With the Coalition for Health AI (CHAI), Duke AI Health,** Federal agencies, and other partners, we are working on establishing a step-wise path forward on AI policy that promotes innovation while providing guardrails for patients. One project, among several, will highlight early examples and potential best practices of AI governance in health care organizations for testing, deployment, and monitoring of AI tools, aiming to create a harmonized framework to help a broader range of health care organizations develop their own governance policies.

> There needs to be near real-time translation between policy makers, developers, and users to ensure that policy is moving with practice.

- **With the University of California, San Francisco Coordinating Center for Diagnostic Excellence (CoDEx)** we will serve as a bidirectional policy translation arm for 10+ demonstration projects being explored across the nation related to the safe, reliable, equitable, effective, and efficient use of clinical AI in health care. Through this work, Duke-Margolis will help shape answers to key digital health policy questions.

- **With the Duke-Margolis Value in Medical Products Consortium,** we are exploring payment for innovative digital health products, including for digital therapeutics, a space that has the potential to substantially expand access to mental health treatment and other therapies. In this work, we are focused on payments that reflect patient outcomes and encourage supporting evidence and further innovation.

Our Foundational Work

The work to advance innovation in biomedical drug and therapy development is at inflection point. We are experiencing an unprecedented era of new biomedical treatments to alleviate some of the most pressing health care challenges. Our work is focused on ensuring that health policy stays in step to ensure these potentially life-changing treatments are informed by real-world evidence and are affordable and accessible for the patients that need them. Following are our current examples of our work to advance biomedical innovation.

- **Evidence Development—**The clinical research enterprise has evolved greatly over the past several decades, with a clear need for evidence-based policy analyses and solutions to better marry clinical care and research, and to address longstanding access barriers that continue to limit representative access to trials for hardly reached populations. **Duke-Margolis is expanding our clinical trials focus in important areas:**

  - **With a coalition of health care leaders.** Duke-Margolis and Duke Clinical Research Institute (DCRI), together with partnering health systems, established the Coalition for Advancing Clinical Trials at the Point-of-Care (ACT@ POC) to address the gaps in timely evidence to inform patient care.

  - **By putting ideas into action.** DCRI and Duke-Margolis are embarking on a project to inform both policy and practice, ultimately improving our understanding of obesity treatments and modern equitable clinical trial conduct.

  - **Through regulatory policy and FDA collaboration.** Duke-Margolis and FDA will work to identify opportunities to clarify regulatory policy to enable innovative methods and operational approaches while maintaining standards in compliance with Good Clinical Practice.

  - **Through Centers for Medicare & Medicaid Services (CMS) and payer collaboration to advance learning health systems.** Duke-Margolis and CMS are collaborating on a series of roundtables to provide more infrastructure and support for learning health system activities.

  - **Through an emphasis on representativeness in clinical trials.** Ensuring that research is conducted in groups representing the diversity of the American population is critical to effectively translate research findings to clinical practice. Duke-Margolis is conducting a project focused on exploring challenges to achieve representativeness and synthesizing best practices.

- **Clarifying the Pathway for Novel Alzheimer's Disease Drugs—**An estimated 12.7 million American over 65 will be living with Alzheimer's disease (AD) by 2050. Important advancements in AD treatments include monoclonal antibodies (mAbs) to target beta-amyloid, which many scientists believe is implicated in AD progression. While evidence of the safety and efficacy of amyloid-targeting AD mAbs treatments continues to emerge through traditional clinical trials, significant questions remain about how to ensure that these treatments are safe and appropriate for real-world use by Medicare beneficiaries and the best ways to advance the evidence development of the impact of these treatments in the context of Medicare coverage.

  Duke-Margolis developed a framework that incorporates two potentially complementary options for a path forward to pursue needed post-market evidence development for AD mAbs treatments. This framework aims to address crucial evidence questions related to Medicare populations by refining and enhancing the adequacy of current and upcoming evidence systems. This forward-looking strategy will not only streamline evidence generation for AD therapies but also contribute to a more robust foundation for informed decision-making in AD health care.

Our work is focused on ensuring that health policy stays in step to ensure potentially life-changing treatments are informed by real-world evidence and are affordable and accessible for the patients that need them.

- **Strengthening Drug Supply Chain Reliability and Leveraging Advanced Manufacturing Technologies—**Manufacturing quality issues, public health emergencies, natural disasters, bioterrorism, geopolitical issues, and other supply and demand shocks all pose threats to patients in need of uninterrupted access to life-saving essential drugs. Duke-Margolis developed the ReVAMP Drug Supply Chain Consortium to generate effective policy solutions that promote a reliable drug supply chain.

  The Consortium focuses on:

  - **supporting a coordinated and sustained federal effort** to promote drug supply chain reliability and advanced manufacturing;

  - **proposing measurement and tracking mechanisms** for drug supply chain reliability;

  - **exploring additional policy and practical approaches** to improve drug supply chain reliability; and

  - **promoting the increased adoption of advanced manufacturing technologies**

  The Consortium's 20 Advisory Group members maintain a persistent focus on chronic shortage issues. Creating a sustained response to the systemic drivers of those issues is challenging. Keeping efforts on the patient and patient impact from shortages can help to ensure continued prioritization of this crucial issue.

• **The State of Real-World Evidence—**Health care stakeholders are enthusiastic to explore whether real-world data sources (RWD), and the evidence they produce (real-world evidence (RWE), can inform and/or hasten medical product development and labeling. Importantly, RWE informs us about patient and provider choices as well as patient outcomes, which helps us understand whether medical products perform as intended in routine care. Ultimately, RWE may drive learning health systems that benefit patients by enhancing precision, equity, and care impact. To guide high-priority efforts aimed at improving the development and use of RWE, Duke-Margolis developed the Real-World Evidence (RWE) Collaborative. With over 40 members, the Collaborative has produced extensive analysis and insight relevant to the FDA's congressionally mandated mission to engage industry, academic, and patient stakeholders with the goal of better translating RWD into RWE to support their regulatory decisions. Duke-Margolis has become a trusted policy development resource for international regulators (e.g., the European Medicines Agency) to advance the use of RWE in product claims and labels related to safety, effectiveness, and comparative effectiveness. Duke-Margolis is also engaging Institute faculty, researchers, students, and external collaborators in RWE policy research that will advance RWE implementation and examine its ethical, legal, and social implications.

Duke-Margolis RWE Collaborative's Five-Year Strategic Plan (2023-2027)

STRATEGIC RWE POLICY PRIORITIES

- Routinely inform regulatory decision-making
- Support reasonable and necessary payer coverage
- Foster collaboration and harmonization across ecosystems, including international agencies
- Integrate research into routine care

Advance Our Work

More support for the Biomedical Innovation portfolio would enable the Duke-Margolis team to proactively lead a dynamic, international conversation on how to improve clinical research evidence generation and could support more point-of-care trial demonstration projects; speed needed drug supply and advanced manufacturing work products and other critical ReVAMP Consortium activities; fund more student, postdoctoral, scholar, and faculty engagement in timely RWE policy research education, hands-on training, and thought collaboration; and help establish a post-market evidence infrastructure for mAbs treatment for Alzheimer's disease that would not only streamline evidence generation for AD therapies but also contribute to a more robust foundation for informed decision-making in AD health care.

Education & Workforce Development

Developing the Next-Generation Health Policy Workforce

Improving access to new medical treatments. Eliminating persistent health inequities. Ensuring availability of affordable and high-quality health insurance. Caring for an aging population Mitigating climate change impacts on population health. Preparing for global pandemics. Optimizing the use of artificial intelligence in health care.

These topics are just a few of the pressing health policy challenges affecting society today.

Tomorrow's health policy professionals will come from a broad range of academic disciplines and perspectives, and will need a cross-cutting toolkit of competencies to anticipate, address, and lead reforms on these complex issues effectively. To meet this need, Duke-Margolis developed a core competency framework to help equip the next generation of the health policy workforce with the necessary knowledge, skills, and attributes to improve health, health equity, and health care through practical, innovative, and evidence-based policy.

Informed by feedback from a broad range of health policy professionals, the Duke-Margolis health policy core competency framework is organized into six domains: **1) health care system & policy process, 2) policy development & evaluation, 3) data & methods, 4) policy translation & communication, 5) networks & relationships,** and **6) leadership & teamwork.**

A competency-informed approach to prepare tomorrow's health policy professionals provides:

- **clarity and consistency** around learning goals and outcomes;
- **connectivity** between curriculum and workforce needs;
- **customization** to individual learner needs, experience, and career paths; and
- **collaboration** between learners, educators, and practitioners to facilitate real-world learning.

Putting the Framework in Action

The health policy core competency framework is designed to be a flexible, adaptive, and practical tool to inform and guide health policy education, training programs, and health policy workforce development more broadly.

At Duke-Margolis, the framework will support a range of efforts, including but not limited to:

- Creating health policy courses and curriculum;
- Evaluating and improving our education and training programs;
- Developing and implementing competency self-assessment activities;
- Launching new initiatives to enhance health policy workforce development; and
- Building partnerships with students, faculty, and other collaborators to foster the development of emerging leaders in health policy.

Core Competencies

Health Care System & Policy Process

Policy Development & Assessment

Data & Methods

Leadership & Teamwork

Networks & Relationships

Policy Translation & Communication

Duke
MARGOLIS INSTITUTE *for* Health Policy

The Duke-Margolis Institute for Health Policy has prioritized its Education portfolio as an opportunity for a pioneering funder to name and impact a key effort to support new student initiatives focused on health policy, expand Duke's community of health policy researchers and faculty who will shape interdisciplinary health policy leaders, and establish a Duke Health Policy Action Fund to support innovative health policy scholarship & solutions for the most pressing health care challenges.

Tomorrow's health policy professionals will come from a broad range of academic disciplines

Our Foundational Work

- **Margolis Scholars Program—**Established in early 2017, the program combines academic and experiential training in health policy and management for exceptional undergraduate, graduate, and professional students from across Duke. This program equips students with the necessary knowledge, skills, and abilities to be the next generation of health care leaders through an innovative curriculum spanning coursework; experiential, hands-on learning; tailored mentorship and advisement; professional development and networking; and a supportive interdisciplinary community of students, faculty, and staff. The Margolis Scholars cohort has grown substantially since its inception, from 5 students in 2017-2018, to 35 students in 2023-2024 from a variety of academic backgrounds across Duke.

"The Margolis Scholars Program has enabled me to understand the broader context of how to translate ideas to policy, what it takes to launch a bipartisan initiative, and how community partners should engage with academia."

Freya Gulamali, BS in Computer Science and
Minor in Chemistry ('25),
Trinity College of Arts and Sciences

- **Undergraduate Health Policy Certificate—**In partnership with the Sanford School of Public Policy, Duke-Margolis offers a certificate program to educate undergraduate students in health policy evidence-based analysis, development, and implementation. Students pursuing the certificate take health policy-relevant courses and also complete applied experiences beyond the classroom. Upon completion of the certificate, students will have the knowledge and basic level skills to pursue entry-level positions in health policy in a variety of settings. The certificate program was established in 2022 and the first cohort will graduate in spring 2024.

- **Summer Experience in Health Policy—**Open to undergraduate and graduate students from Duke and other universities, this 10-week summer internship offers students experiential opportunities to contribute to a variety of health policy projects through a collaborative and mentored experience at our Durham, NC, or Washington, DC offices. Through the program, interns gain experience in qualitative and quantitative research; receive training on research skills, presentations, and writing; participate in Margolis Seminars; and build relationships with their peers. At the end of the program, students present their final work at the Summer Research Showcase. 2024 marks the seventh year of our summer internship program that to date has provided more than 160 interns with experience in health policy.

- **Bass Connections Health Policy and Innovation Theme—**Bass Connections brings Duke students, staff, and faculty together to address complex societal problems through collaborative research projects under certain themes. Duke-Margolis has led numerous project teams since the Institute's inception in 2016, and in 2022 established a theme in Health Policy and Innovation. This theme has grown to 15 ongoing project teams in 2024-2025, using an interdisciplinary approach to confront U.S. challenges in health and health care through health policy.

- **Postdoctoral Fellowship and Affiliated Fellow Program—**The Duke-Margolis Postdoctoral Program in Health Policy aims to advance critical health policy research while building a pipeline of well-trained young leaders able to translate scientific research into practical policy solutions. The Health Equity Policy & Primary Care Fellowship is offered in collaboration with the Duke Department of Family Medicine and Community Health and aims to equip clinicians with the knowledge and experience to translate the concepts of health equity and health policy to improve their clinical knowledge. The National Clinician Scholars Program at Duke University, led by the Schools of Medicine and Nursing and in collaboration with the Durham Veterans Affairs, trains nurse and physician researchers to become change agents driving policy-relevant research and partnerships to improve health and health care.

- **Academic Programs—**Duke-Margolis offers Health, Health Care, and Health Policy-Related Courses to educate and train the next generation of health policy professionals. Numerous Duke-Margolis faculty and researchers teach these courses to expand and deepen health policy curriculum at Duke.

- **Health Equity Education Initiative**s are based on a strategy that integrates anti-racism and equity knowledge and tools into our educational programs. As part of this strategy, we have created a toolkit to synthesize key literature and activities for integrating health equity into the health policy curriculum, and developed health equity for health policy core competencies to increase knowledge among all learner levels.

- Our seminar series, **Duke-Margolis Seminar in Health Policy & Management,** connects the Duke-wide health policy community and provides faculty, researchers, and students with an opportunity for feedback on their health policy-related work. The seminars cover policy analysis in progress, emerging or newly-released research, and the policy impact of health-related legislation and regulations. Looking ahead, the Grover Lectureship will provide an opportunity to bring academic leaders in health policy beyond Duke and expand our national community and impact.

Advance Our Work

Additional support would advance the Duke-Margolis Education and Workforce Development portfolio in a host of ways, including importantly the ability to:

- extend support to additional students annually
- increase program support to expand the development of new health policy courses
- support faculty members and their teaching and research through new case development, designing collaborative course projects, and connecting faculty and health policy leaders
- create a formal internship/fellowship program which partners with leading private and public health care organizations to provide additional experiential learning for students
- support postdoctoral fellows and summer internship students who are focused on health policy

21ˢᵗ Century Public Health

Strengthening Public Health and Health Care Partnerships for the Future

Progress on America's health has been challenging, despite access to better tools and capabilities to improve health than ever before. The United States has world-leading diagnostic tests, treatments, and vaccines; increasingly rich and interoperable electronic health data to help patients stay healthier; and many innovative efforts by health care organizations to strengthen primary and preventive care, including care provided at home. Yet, American life expectancy has declined and many health disparities have widened in recent years, alongside rising health care spending with growing challenges in affordability and access. Health care workers are also reporting more burnout and attrition than ever before.

It is time for a more collaborative path forward on improving the nation's health. In partnership with the National Academy of Medicine (NAM) and a leading set of multi-stakeholder collaborators, Duke-Margolis is working to outline a set of feasible, meaningful action steps across health care, public health, and community supports to improve our nation's capacity to help Americans stay healthy in the near term. These action steps advance the longer-term goal of bringing together public, private, and community organizations to strengthen the nation's public health capabilities in critical areas of population health need.

Why This Work Matters

Recent reports have noted critical gaps in authority and resources for federal, state, and local public health agencies to fulfill their mission of preventing disease and advancing population health at the community level. In many ways, these gaps are not new: funding has largely been flat or negative for decades, and much of actual expenditures are for programs targeted to fill gaps in particular health care needs for uninsured and underinsured individuals with certain conditions, particularly infectious diseases. But in other areas, such as trust in public health, the challenges seem to be worsening.

Several other simultaneous trends increase the urgency of addressing these gaps, but also suggest opportunities for a new approach to support and leverage efforts of public health agencies and health care providers to improve population health, including:

- **Opportunity:** The continuing rise in biomedical capabilities to help address population health threats, including the deployment of repurposed treatments and development of targeted new treatments, the rapid development and large-scale production of multiple safe and effective vaccines for emerging health threats, and the capacity to deliver these interventions through comprehensive "test to treat" strategies

- **Challenge:** The gap between test to treat biomedical capabilities and their consistent impact on population health can be substantial across disease areas

- **Opportunity:** The development of partnerships between health care, public health, and other public and private entities to address population health challenges, including the collection of data to provide a comprehensive picture of the health of communities and populations in real time

- **Challenge:** The growth of health care resources has long outpaced those for traditional public health institutions. Public health care funding has been important to advance state and local data collection across disease surveillance and other public health-oriented data flows about community health risks. If paired with increasingly interoperable medical records, registries, and other health care data systems and advances in digital technologies and real-world

evidence, public health care funding could further facilitate partnerships between public health and health care providers to intercept and address health risks earlier.

- **Opportunity:** Health care organizations are increasingly engaged in addressing social factors that create barriers to care and health, including food insecurity, inadequate housing, and other "non-medical" barriers to access, which could interdigitate with and augment social services and public health interventions at the state and local level if better coordinated.

- **Opportunity:** The federal government, state, employer, and other purchaser efforts are supporting payment and care reforms aiming to achieve better health care results through greater accountability for health not just excellence in traditional medical services.

Altogether, these trends could support a re-envisioning of how public health, health care, and social service systems can work together to address population health challenges. But there is not yet a systematic vision or strategy for whether and how these trends in health care capabilities and financing can best support public health goals, including addressing disparities in health and the downward trend in health outcomes across many population groups.

It is time for a more collaborative path forward to improve the nation's health.

Finding Solutions

In a May 2023 issue brief, Duke-Margolis authors,together with now CDC Director Mandy Cohen, outlined a path toward realizing these aims—Accountable Population Health, focused on more intentional partnerships between health care and public health to achieve population health goals.

Building from this, spring 2024 efforts have focused on practical, collaborative short-term action steps to address two key health challenges as proof of concept for amplifying concerted public health and health care actions across other major population health challenges:

- strengthening protections for individuals and communities from the complications and disruptions of respiratory infections
- preventing overdose deaths and other complications of opioid use disorder (OUD).

We have outlined how federal agencies can collaborate to support evidence-based, short-term actions largely with existing authorities. Our goal is measurable progress toward improving the nation's health within the next 18 months and providing a foundation for further progress.

Duke-Margolis has also prioritized population-level strategies for specific disease areas (e.g., hepatitis C and Alzheimer's disease, comprehensive approaches for multi-illness fall respiratory viruses) for pioneering funders who want to advance health policy to strengthen public health programs, further the development of an interdisciplinary data infrastructure model that gives care organizations and communities real-time information they can act on together, support new student initiatives and scholarships, and expand Duke's community of health policy faculty and researchers to advance collaborative, accountable population health.

Our Foundational Work

Duke-Margolis is continuing to expand its policy work at the interface of public health and health care reform, including the advancement of population health models and public health capabilities.

- **Public Health 3.0 and Accountable Population Health—**Public health institutions have critical analytic capabilities and expertise to support population health efforts, but lack funding and local intervention capabilities to be accountable for public or population health goals. Health care providers mostly continue to rely on payment models that provide limited support for "upstream" measures, such as surveillance of health risks, preventive steps, early detection, and treatment—despite advancements in biomedical technologies, data, and support systems that enable coordination of programs to improve population health and address health inequities.

  Opportunity and momentum exist to re-envision Public Health 3.0. The Accountable Population Health model describes a partnership among health care, public health, and social service programs to implement more sustainably funded data, support, and care delivery capabilities within communities to address population health challenges. In this approach, Public Health 3.0 priorities can be addressed by updating the expectations and responsibilities of public health and publicly-supported, largely private health care systems.

The Accountable Population Health approach could be initially applied in three key ways:

- **Provide foundational data for situational awareness of urgent community health risks** and for determining actionable, feasible steps to make measurable progress across health care, public health, and social services.

- **Advance population test to treat initiatives** related to public health goals using accountable health care reforms

- **Build on better situational awareness and improve test to treat capabilities** by addressing public health threats that are not well supported in most fee-for-services based health care systems today.

• **Advancing Hepatitis C Elimination—**Duke-Margolis has been instrumental in advancing a national strategy to reduce the burden of hepatitis C in the United States. Over two million Americans suffer from chronic hepatitis C, which remains the leading cause of liver cancer and transplantation despite the notable biomedical progress over the past decade.

The care cascade for hepatitis C includes a two-step diagnostic process followed by prescription and adherence to curative, direct acting antiviral (DAA) therapy. A proposed five-year national program for hepatitis C elimination prioritizes broad access to DAA treatment and development of point-of-care diagnostics, accompanied by public health programming focused on educating physician and patient communities on hepatitis C. **Duke-Margolis developed this comprehensive, coordinated national approach to hepatitis C elimination with an evidence-based implementation plan, and with an emphasis on leveraging existing health care and public health programs whenever possible.**

Duke-Margolis recommendations focus on opportunities to advance hepatitis C elimination at the population level by integrating public health, health care, and social services to provide comprehensive whole-person care that ensure treatment continuity and, ultimately, cure the disease for a greater number of patients. Our aim is to address two challenges to treat hepatitis C: the need for person-focused payment and care models, and the need to expand care models that address the associated health and social needs of people with or at risk of hepatitis C.

Advancing Hepatitis C Elimination:
A Coordinated Public Health and Health Care Strategy
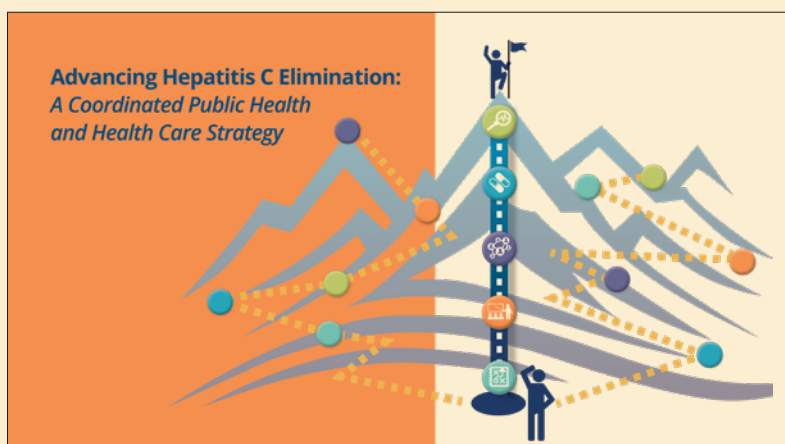
• **Supporting Traditionally Underserved Populations through Better Safety Net and Home-based Care—**Safety net providers remain underrepresented in value-based payment (VBP) models due to design limitations and insufficient resources, despite the potential benefits of these models to support more coordinated, comprehensive care. Efforts to close this gap are critical to the CMS strategic vision for transitioning Medicare and Medicaid patients into accountable care relationships by 2030.

Policy Opportunities to Improve Care in the Safety Net through Accountable, Value-Based Payment Reform
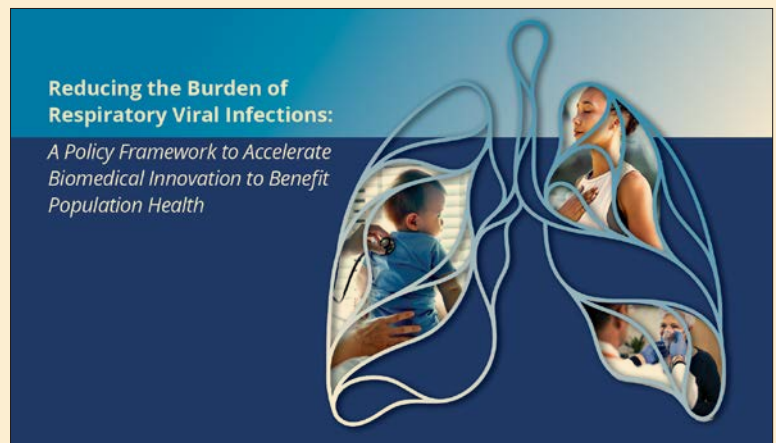
Another key underserved population are people who are homebound with complex health and social needs and would benefit from receiving care in the home or community settings. The COVID-19 pandemic accelerated the shift to home settings as providers rapidly pivoted to delivering care outside of traditional clinical and institutional settings. Despite this temporary expansion, the home setting remains unevenly used and underutilized.

Duke-Margolis work to advance health policy for these underserved communities provides practical, evidence-based guidance for designing value-based payment models that can inform federal and state initiatives to better support safety net institutions and improve care for historically underserved and under-resourced communities—initiatives that exist at the intersection of health care, public health, and social services. The Duke-Margolis report, "Policy Opportunities to Improve Care in the Safety Net through Accountable, Value-Based Payment Reform," with support from The Commonwealth Fund and Arnold Ventures,, examines the opportunities—and the challenges—with advancing safety net providers in VBP models.

For the homebound population, Duke-Margolis is working to develop evidence-based policy recommendations, translate policy considerations to providers, and share practical guidance to policymakers to advance better home-based care.

• **Reducing the Burden of Respiratory Viral Infections—**Duke-Margolis is advancing a project focused on reducing the burden of viral respiratory disease through medical products that target transmission. Advances in biomedical innovation are creating an unprecedented opportunity to lower the impact of respiratory diseases like COVID-19, RSV, and influenza, through products that benefit individuals who use them to avoid infection or reduce the duration/severity of symptoms benefit those around them, thus providing population health and public health benefits to the community.

However, U.S. and global public policies do not have clear, well-developed frameworks and policies to support the development, access, and use of innovations that confer population health benefits. This project aims to define a policy framework to explicitly account for the population health benefits of transmission reduction, to identify feasible steps to develop an evidence generation framework that captures population health benefits, and regulatory reforms to further the development and further regulatory reforms to advance the development and use of these products.. Widespread use of these products can ultimately help communities better prepare for and reduce the spread of infectious disease.

Reducing the Burden of Respiratory Viral Infections:

A Policy Framework to Accelerate Biomedical Innovation to Benefit Population Health

Advance Our Work

We are seeking funding to advance our work across these areas and further reinforce the connections among public health, health care, and social service reforms described above. We also seek to establish new student initiatives and scholarships focused on health policy and public health, to expand Duke's community of health policy researchers and faculty, and to establish a Duke Health Policy Action Fund, which will provide start-up support for innovative health policy scholarship and solutions to address pressing public health challenges.

2024 Issue, Initiatives, and Impact Report

Advance Tomorrow's Health Care Leaders

The nation needs a new and diverse generation of health care leaders to make the vision of high-quality, affordable, and equitable health care a reality. We are preparing those leaders through our interdisciplinary approach that engages not only faculty, schools, and units across Duke but also the disciplines of policy, medicine, engineering, law, nursing, business, and the humanities. Whether engaging with Duke-Margolis at the undergraduate, graduate, or postdoctoral level, we ensure that our students gain the analytic, communications, and leadership skills necessary to lead solutions in the ever-complex health care environment.

Our students and graduates gain the analytic, communications, and leadership skills necessary to lead solutions in the ever-complex health care environment.

2023-2024 Duke-Margolis Scholars

Jada Allen
BA '25
Sanford School of Public Policy

Breanna Barrett
BA '25
Trinity College of Arts and Sciences

Nikhil Chaudhry
BA/BS '23
Trinity College of Arts and Sciences

Alexa Chronister
JD '24
School of Law

Allison Chu
MD '25
School of Medicine

Winifred Edom
MS '24
Duke Global Health Institute

Jillian Foye
MPP '25/JD '25
Sanford and UNC School of Law

Freya Gulamali
BA '25
Trinity College of Arts and Sciences

Hudson Hazlewood
MS '25
School of Medicine

Ro Huang
BA '24
Trinity College of Arts and Sciences

Laila Issa
MPP '25
Sanford School of Public Policy

Shewit Jaynes
PhD '26
School of Nursing

Elaijah Lapay
BA '24
Trinity College of Arts and Sciences

Katie Lazar
MPP '25
Sanford School of Public Policy

Rose Lee
BA '24
Trinity College of Arts and Sciences

Rewa Malhotra
MBA '24
Fuqua School of Business

Katherine Drew Marapese
MBA '25
Fuqua School of Business

Riya Mohan
BA '24
Trinity College of Arts and Sciences

Vibhav Nandagiri
BA '25
Trinity College of Arts and Sciences

Kartik Pejavara
BA '24
Trinity College of Arts and Sciences

Jack Pitsor
MPP '24
Sanford School of Public Policy

Sai Rachakonda
BA '24
Trinity College of Arts and Sciences

Fariha Rahman
MS '25
School of Medicine

Estefania Rodriguez-Martinez
MIDP '24
Sanford School of Public Policy

Ashna Sai
BA '25
Trinity College

Karnika Singh
PhD '26
Pratt School of Engineering

Tim Southam
JD '25
School of Law

Laura Stilwell
MD/PhD '25
School of Medicine

Ginny Tsao
MBA '24
Fuqua School of Business

Erin Van Gessel
ABSN '24
School of Nursing

Ben Verschoore
MBA '25
Fuqua School of Business

Kathrine Wetherbee
MPP '24
Sanford School of Public Policy

Kristian Wright
JD '24
School of Law

For more information about the Duke-Margolis Institute for Health Policy, please visit our web site **healthpolicy.duke.edu**

To learn how you can be involved in, advance, and support our mission to make health care better, more equitable, and more affordable, please contact, Patricia S. Green, Director of Communications, **patricia.s.green@duke.edu**

1201 Pennsylvania Avenue
Suite 500
Washington, DC 20004

Duke University
230 Science Drive
Durham, NC 27708